United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program

SOP No.: PDP-ADMIN-7		Page 1 of 8
Title: Preparation of Standard Operating Procedures (SOPs)		
Revision: 4	Replaces: 5/2/94 and SAMP-	Effective: 9/13/96

1. Purpose:

To provide uniform and standardized guidelines to all participants in the USDA/AMS-Pesticide Data Program (PDP). These guidelines detail the components of a standard operating procedure (SOP) and the structure of the SOP system for PDP residue studies.

2. Scope:

This standard operating procedure (SOP) shall be followed by USDA/AMS and all facilities involved in the collection of samples and performance of analytical determinations for USDA/AMS-PDP, including those laboratories which are conducting residue studies for PDP and support laboratories conducting stability or other types of studies which may impact the program.

3. Outline of Procedure:

5.1 Description of an SOP
5.2 Components of an SOP
5.3 USDA/AMS-PDP SOPs
5.4 USDA/AMS-PDP Internal SOPs
5.5 Sampling Internal SOPs
5.6 Laboratory Internal SOPs

4. References:

USDA/AMS-PDP GLP Meeting, Minutes, April 27-29, 1992

Jon McNeal, Branch Chief, USDA/AMS-Technical Services, Communication to William Franks, Jr., May 8, 1991

Garfield, Quality Assurance Principles for Analytical Laboratories, Pg. 9, 1991

U.S. EPA SOP No. GLP-S-01, Preparation of Standard Operation Procedures, October 1, 1990

U.S. EPA, Standard Operating Procedures, 40 CFR part 160.81, August 17, 1989

Taylor, Quality Assurance of Chemical Measurements, pp. 85, 90, 113, 114, 173, 210, 223, 236, 261, and 262, 1989

5. Specific Procedures:

5.1 Description of an SOP

a. SOPs are written instructions on how to perform tasks and give instructions for procedures. The task or procedure is to be performed in an optimized and consistent manner as described by the document.

b. The SOPs are intended to assure consistency of data, quality, and procedures throughout the PDP residue studies.

c. In addition, SOPs are utilized for audit or review purposes.

5.2 Components of an SOP

a. This SOP serves as an example of the basic components to be included in the preparation of an SOP. There shall be a Purpose, Scope, Outline, References (if any), the Specific Procedure, and signatures with dates. Sampling facilities shall be permitted to restructure the format of their internal SOPs if desired.

b. The Specific Procedure shall be written in precise and explicit terminology. Outline form is acceptable.

c. UDSA/AMS-PDP and participating laboratory SOPs shall be identified with an introduction (or header) box giving the SOP number, title, revision number, replacement identification, and effective date. Sampling SOPs need only be identified with a title, revision number, and effective date.

d. Tables, attachments and appendices may be placed at the end of the document if they are required. Shorter tables and any figures shall normally be inserted in the text, if they are required.

e. Standard abbreviations (i.e., EPA, USDA, AMS, CFR) may be used without further identification. Other names or terms, when first used in an SOP, shall be written in full with the accepted acronym in parenthesis immediately following.

f. The SOP is intended to provide consistency in the conduct of routine operations and to serve as a guide for the conduct of audits. It is not intended to replace experience and basic training but may be used as a training tool.

g. The SOP shall address each specific area of the topic it is intended to address. The SOP shall specifically identify the raw data to be generated as well as all other information required to prepare the end product of the topic of the SOP.

5.3 USDA/AMS-PDP SOPs

a. USDA/AMS shall provide SOPs giving the requirements for common aspects and of the program, and specific requirements as needed. These include SOPs in the areas of:

1. Administrative Procedures;
2. Sampling Procedures;
3. Standards;
4. Laboratory Operations;
5. Data Handling;
6. Instrumentation;
7. Quality Control.

b All USDA/AMS SOPs shall be considered directive in principle, unless the SOP explicitly states that the SOP or a section of the SOP is suggestive in nature.

c. USDA/AMS shall have immediately available manuals and SOPs relative to the laboratory or field procedures being performed. Published literature

may be used as a supplement to SOPs.

d. Each USDA/AMS SOP shall be approved and signed by at least two of the following: the USDA/AMS Administrative Director, Technical Director, or Quality Assurance Officer (QAO).

e. All SOPS shall be reviewed annually. The USDA/AMS QAO shall assure that the SOPs are reviewed and updated as necessary.

f. An index of PDP SOPs shall be maintained by the USDA/AMS QAO. The updated index shall be distributed along with any SOP revisions.

g. Distribution of the SOPs, original and subsequent revisions, shall include the USDA/AMS Administrative and Technical Directors, and Archives, participating facilities' Administrative Managers, Sampling and Technical Program Managers, QAOs, and Archives, and all other applicable personnel.

5.4 Sampling Internal SOPs

Each participating State/Agency performing sample collection for PDP shall prepare internal SOPs giving specific details of procedures utilized to comply with the USDA/AMS SOPs. In this manner, each facility shall have some flexibility to adapt their individual procedures to the overall program requirements.

a. The participating facilities shall have SOPs in writing setting forth specific procedures and methods that management is satisfied are adequate to assure the quality and integrity of PDP sample data.

b. Each sampling facility shall have immediately available manuals and SOPs relative to the procedures being performed. Published literature may be used as a supplement to SOPs.

c. Each facility shall have their SOPs available for inspection by authorized employees or duly designated representatives of USDA/AMS during sampling reviews.

d. Each SOP shall be approved by at least two of the following: the author, the participating facility Sampling Manager, or the participating facility Sampling Administrative Manager. The signature block for each approval shall contain the handwritten signature, the printed name, title, and date. Address and telephone number shall be included if the individual is not based at the facility.

e. Any deviations from the requirements of the USDA/AMS SOPs shall be authorized in writing by the USDA/AMS Technical Director and QAO and documented by the sampling facility. Written authorization shall be kept

on file by USDA/AMS as well as the participant's Sampling Manager.

f. SOPs shall be modified, added to or updated during the year if major changes in content are necessary due to operational or policy changes.

g. Each participating sampling facility shall maintain an index of their internal SOPs. SOPs or additional information may be requested by USDA/AMS.

h. Distribution of the internal SOPs, original and subsequent revisions, shall include the participant's Administrative Manager, Sampling Manager, Archives, and each affected employee in the facility.

j. The facilities' SOPs shall follow the criteria of this document.

5.5 Laboratory Internal SOPs

Each laboratory shall prepare SOPs giving specific details of procedures utilized to comply with the USDA/AMS SOPs. In this manner, each laboratory shall have some flexibility to adapt their individual procedures to the overall program requirements.

a. The testing laboratories shall have SOPs in writing setting forth procedures and methods that management is satisfied are adequate to ensure the quality and integrity of the data generated in the course of a study.

b. Each laboratory or other study area shall have immediately available manuals and SOPs relative to the procedures being performed. Published literature may be used as a supplement to SOPs.

c. Each laboratory shall have their SOPs available for inspection by authorized employees or duly designated representatives of USDA/AMS during laboratory reviews.

d. Each internal SOP shall be approved and signed by the QAO and at least one of the following: the author, the participating laboratory

Administrative Manager, or the Technical Program Manager. The signature block for each approval shall contain the handwritten signature, the printed name, title, and date. Address and telephone number shall be included if the individual is not based at the laboratory.

e. Any deviation from a USDA/AMS SOP shall be authorized in writing by the USDA/AMS Technical Director and QAO and shall be documented by the laboratory in the raw data. Written authorization shall be kept on file by USDA/AMS as well as the participating laboratory QAO.

f. SOPs shall be modified, added to, or updated during the year if major changes in content are necessary due to operational or policy changes. Revisions shall be approved and signed as stated in 5.5.d. The Technical Program Manager is responsible for administering local changes.

g. Each participating laboratory shall maintain an index of their internal SOPs. SOPs or additional information may be requested by USDA/AMS.

h. Distribution shall include the participating laboratory Administrative Manager, Technical Program Manager, QAO, Archives, and each affected employee in the laboratory.

i. The laboratory SOPs shall follow the criteria of this document.

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